OCT 3 1 2001

K01 3504
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510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter: William Skremsky
CTI PET Systems, Inc.
810 Innovation Drive
Knoxville, TN 37932

Telephone No: (865) 218-2522
Fax No: (865) 218-3000

Date of preparation: October 8, 2001

Identification of the Product

Device Proprietary Name: ECAT LSO PET/CT Scanner
Common Name: Combination Positron Emission Tomography (PET) and X-Ray Computed Tomography (CT)
Classification Name: Emission Computed Tomography System per 21 CFR 892.1200

Marketed Device to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT PET/CT	CTI PET Systems (CPS)	K002715

Device Description and Comparison

The ECAT LSO PET/CT is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. This dual modality tomograph is a modified version of the ECAT PET/CT (K002715) and will utilize the same CT component from the Siemens SOMATOM Project 10 EMOTION (CT) scanner. However, in place of the ECAT HR+ PET component that uses 288 BGO crystal block detectors, the ECAT LSO PET/CT will be configured with the CPS ECAT ACCEL PET (K002584) using 144 LSO crystal block detectors, in combination with the Siemens Somatom CT. As with the predicate system, 2D PET acquisition septa and the PET transmission sources are not included in the modified ECAT LSO PET/CT. PET emission data is acquired only in 3D and PET attenuation correction map data is obtained from the CT. The PET and CT components will be contained within the same unified housing used on the original ECAT PET/CT to create an integrated, PET, CT, and combined PET/CT, tomographic imaging system.

The ECAT LSO PET/CT gantry structure, patient handling system (PHS), advanced computational system (ACS 3), workstation and software will remain essentially the same as the ECAT PET/CT with only minor modifications to accommodate the different PET detectors. In addition, the ECAT LSO PET/CT as well as the HR+ based ECAT PET/CT will also be offered with either the Siemens single slice EMOTION CT (K991764) or the dual slice Duo version, SOMATOM EMOTION MS (K003014), for the CT component of the system. The EMOTION MS CT with two rows of X-ray detectors provides the capability for faster CT acquisitions but does not otherwise affect performance of the ECAT LSO PET/CT.

The ECAT LSO PET/CT scanner is intended for use primarily as a clinical, whole-body oncology machine with mid-range spiral CT performance and fast patient-throughput clinical PET performance. The CT component will also enhance PET scans by allowing fast, essentially noise-free attenuation correction for PET studies, and by providing precise anatomical reference through fused PET and CT images. In addition, the ECAT LSO PET/CT will retain mechanical isolation and independent functionality of the PET and CT scanning systems, thereby allowing for most standard CT and PET clinical diagnostic protocols to be available on the PET/CT system.

Indications for Use

The CPS/Siemens ECAT PET/CT system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. The PET/CT scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

The PET and the CT functions of this system can also be used in combination to provide high resolution, noise free CT attenuation correction maps for PET images and, additionally, utilized to produce fused CT and PET images, providing detailed anatomic and metabolic function information in a single image.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube and the simultaneous translation of the patient.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2001

Mr. William Skremsky
Senior Regulatory Affairs Specialist
CTI, Inc.
810 Innovation Drive
KNOXVILLE TENNESSEE 37932

Re: K013504
Trade/Device Name: Modification to: ECAT LSO PET/CT Scanner
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: October 18, 2001
Received: October 22, 2001

Dear Mr. Skremsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013504

Device Name: ECAT LSO PET/CT Scanner

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013504